

Notice of Allowability

Application No.

10/678,927

Examiner

Abdel A. Mohamed

Applicant(s)

GOULD ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment, remarks, evidence and IDS filed 4/27/07 and telephonic interview of 7/12/07.
2. ☒ The allowed claim(s) is/are 22-25,27,28,30,31,33,34 and 36-38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070716</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>4/27/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/07 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, EVIDENCE, IDS AND STATUS OF THE CLAIMS

2. The amendment, remarks, evidence and information disclosure statement and Form PTO-1449 filed on 04/27/07 are acknowledged, entered and considered. In view of Applicant's request claim 22 has been amended. Claims 22-25, 27-31, 33, 34 and 36-38 are now pending in the application. The objection and rejection under 35 U.S.C. 103(a) over the prior art of record is withdrawn in view of Applicant's amendment, remarks and submission of evidence filed on 04/27/07.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

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by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Authorization for this examiner's amendment was given in a telephone interview with Patrick G. Gattari on 07/12/07.

5. The application has been amended as follows:

Cancel claim 29.

Replace the claims as follows.

22. (Currently amended) A method of maintaining mean circulating hemoglobin (Hb) levels above 5.0 g/dL in a patient suffering from massive blood loss comprising administering to the said patient a polymerized hemoglobin solution in an amount of at least one blood volume of the said patient, wherein the administration of the solution avoids vasoconstriction, and renal, pancreatic, gastrointestinal and cardiac dysfunction associated with the administration of unmodified hemoglobin solution when treating massive blood loss.

30. (Currently amended) A method for treating a human having a hemoglobin concentration below about 7 g/dL as the result of a massive blood loss ~~and~~, comprising administering to the said human a polymerized hemoglobin solution in an amount above 5L sufficient to maintain arterial pressure above 60 mmHg.

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37. (Currently amended) ~~The method of claim 30~~ A method for treating a human having a hemoglobin concentration below about 7 g/dL as the result of a massive blood loss comprising administering to said human a polymerized hemoglobin solution in an amount above 5L sufficient to maintain arterial pressure above 60 mmHg, wherein the administration of the solution avoids the toxicities associated with vasoconstriction, and renal, pancreatic, gastrointestinal and cardiac dysfunction associated with the administration of unmodified hemoglobin solution when treating massive blood loss.

REASONS FOR ALLOWANCE

6. The following is an examiner's statement of reasons for allowance: The rejection under 35 U.S.C. 103(a) over the prior art of record is withdrawn in view of the evidence provided as Exhibit A which is an article by current inventors Gould et al, The Life-Sustaining Capacity of Human Polymerized Hemoglobin when Red Cells be Unavailable, J. Amer. Coll. Surg. (2002) 195(4):445-455. Following the article, Dr. Maier (Expert in this field) comments by stating that at the time the invention was made one of skill in the art would not have been motivated to use high volumes of hemoglobin solution for treating patients with massive blood loss because one of skill in the art would have expected significant organ failure when dosed with volumes of hemoglobin solution greater than 5L. Thus, the evidence shows unexpected results as confirmed by the expert Dr. Maier.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION AND FUTURE CORRESPONDANCE

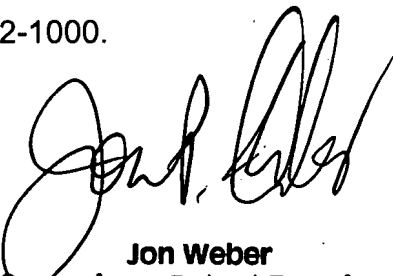
7. Claims 22-25, 27, 28, 30, 31, 33, 34 and 36-38 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jon Weber
Supervisory Patent Examiner



Mohamed/AAM
July 16, 2005